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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,428	11/15/2001	Avi J. Ashkenazi	P2730P1C44	6441

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,428	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-118 and adding new claims 119-131, filed on 15 November 2001 is acknowledged.

Thus claims 119-131 are pending and under consideration.

Priority:

2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure in application serial no. 09/941,992, filed on 28 August 2001, because, although the claimed PRO1245 nucleic acid and the encoded PRO1245 polypeptide are disclosed as SEQ ID NOs:407 and 408, respectively, in application 09/941,992, none of the parent applications provide a specific and substantial asserted utility or a well established utility for the claimed invention. Accordingly, the subject matter defined in claims 119-131, is afforded an effective filing date of 11/15/2001, which is the filing date of the current application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 11/15/2001, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 11/15/2001.

Information Disclosure Statement:

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3a. The information disclosure statements filed 17 September 2002 and 31 May 2002 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because they fail to identify each reference by author and publication date. They have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification:

4a. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5a. Claims 119-131 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 119-131 of the instant invention are directed to an isolated polypeptide of SEQ ID NO:408. The specification designates the polypeptide of SEQ ID NO:408, as PRO1245, and describes it as being a human polypeptide that comprises 104 amino acid residues, (figure 290). The specification demonstrates that the genes encoding the PRO1245 along with genes that encode many of the other proteins disclosed by the instant specification, are expressed in lung and colon primary tumors and cell line models, (see Example 170 on page 539 and table 9B on pages 552-553). However, it does not describe the significance of this expression, nor does it compare the expression of the PRO1245 protein in normal lung and colon tissues to the expression of said protein in the lung and colon tumors or cell lines. The specification establishes no connection between the expression of said polypeptide and developing lung or colon tumors. The

specification does not disclose an activity for the PRO1245 polypeptide, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application, based solely it might be expressed in some primary lung or colon tumors or cell lines. Thus the PRO1245 polypeptide lacks a specific or substantial utility or a well established utility.

5b. Claims 119-131 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. No biological activity was assayed or determined for the PRO1245 polypeptide. Therefore, there is no

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Although the specification describes the structure of PRO1245 polypeptide, the skilled artisan would not know how to use said PRO1245 polypeptide, because Applicants do not provide any information regarding biological activity or physiological significance of said polypeptide. Instant specification also fails to establish a correlation between the polypeptide of the instant invention and a disease state or condition.

5c. Claims 119-123 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 14, instant specification would still fail to adequately describe and enable an isolated polypeptide comprising an amino acid sequence that is at least 80%, 85%, 90%, 95% or 99% to the polypeptide of SEQ ID NO:408. Claims 119-123 are drawn to a polypeptide having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence. The specification does not provide any particular conserved structure, or other distinguishing features which would enable a polypeptide having at least 80%, 85%, 90%, 95% or 99% to the polypeptide of SEQ ID NO:408 that would retain the activity of the polypeptide of SEQ ID NO:408. Claims 119-124, 127 recite an amino acid sequence of the extracellular domain of the polypeptide of SEQ ID NO:408. However, the specification does not provide written description for said extracellular domain, since it does not teach which residues of the polypeptide of SEQ ID NO:408

represent said extracellular domain. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement

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that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

Therefore, only the isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 408, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim rejections-35 USC § 102(b):

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 119-131 are rejected under 35 U.S.C § 102(b) as being anticipated by GENENTECH INC. (GETH), (WO 99/63088, December/1999); DIADEXUS LLC. (DIAD), (WO 99/60160 November/1999); INCYTE (INCY), (WO 00/00610, June/2000).

Each of references, GETH, DIAD and INCY, discloses an isolated polypeptide that shares 100% amino acid sequence identity to the amino acid sequence of the polypeptide of SEQ ID NO:408, recited in claims 119-125, 129-131 of the instant application . See attached copies of the comparison of SEQ ID NOs:408, claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'A', 'B', 'C'). Regarding claim 129, it is understood that the deposited sequence encodes the polypeptide of SEQ ID NO:408, therefore, since the polypeptide disclosed by each of the above references shares 100% identity to the polypeptide of SEQ ID NO:408, these references also anticipate claim 129. With respect to claims 130 and

131, each of the cited references also discloses a chimeric or fusion protein comprising its polypeptide and a heterologous polypeptide, (see for example the MILL reference, pages 65-68). With respect to claim 126, GETH teaches a polypeptide that lacks its associated signal, (see claim 24).

Therefore the GETH, DIAD and INCY references, all anticipate the instant claims 119-125, 129-131 in the absence of any evidence to the contrary.

Claim rejections-35 USC § 102(a):

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6b. Claims 119-125 and 129 are rejected under 35 U.S.C § 102(a) as being anticipated by Krop et al (Augustr/2001).

Krop et al (Accession Number Q96qr1), disclose an isolated polypeptide that shares 100% amino acid sequence identity to the amino acid sequence of the polypeptide of SEQ ID NO:408, recited in claims 119-125 and 129 of the instant application . See attached copies of the comparison of SEQ ID NOs:408, claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'D'). Regarding claim 129, it is understood that the deposited sequence encodes the polypeptide of SEQ ID NO:408, therefore, since the polypeptide disclosed by Krop et al reference shares 100% identity to the polypeptide of SEQ ID NO:408, this reference also anticipates claim 129.

Therefore the Krop et al reference anticipates the instant claims 119-125 and 129 in the absence of any evidence to the contrary.

Conclusion:

7. No claim is allowed.


Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
08 April 2004


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